

Research and Special Programs Administration MAR 24 2000

400 Seventh Street, S.W. Washington, D.C. 20590

Edward Krisiunas, MT(ASCP), CIC, MPH Director, Inscite 115 Lyons Road Burlington, CT 06013

Reference No. 99-0106

Dear Mr. Krisiunas:

This is in response to your letter concerning a provision in 49 CFR 173.134 that excepts waste transported from households from regulation under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). You asked for a clarification of what constitutes household waste. You also asked us to explain why regulated medical waste (RMW) that is transported by a courier from a physician's office is regulated under the HMR but it is not regulated when generated by a home health care provider and discarded in household waste. I apologize for the delay in responding and any inconvenience this may have caused.

Household waste is not subject to the requirements in the HMR. (See § 173.134(b)(1)(v).) In 1989, the Environmental Protection Agency (EPA) published an interim final rule (54 FR 12326, 12339) that implemented a two-year demonstration program for regulating medical waste. EPA excluded from regulation medical waste from households, including that generated by a home health care provider. I have enclosed a copy of the preamble discussion on household waste that appeared in the EPA final rule. We agreed with EPA's position. When we amended our infectious substance requirements in the HMR and added a definition for RMW, we provided a similar exclusion for household waste (56 FR 66124, 66142).

I hope this satisfies your request.

Sincerely,

Hattie L. Mitchell, Chief

Regulatory Review and Reinvention

Office of Hazardous Materials Standards

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Enclosures



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99-0106

April 14, 1999

Hattie Mitchell
U.S. Department of Transportation
Research and Special Programs Administration Program
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Washington, D.C. 20509

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Dear Ms. Mitchell,

I am writing in response to your letter to Dr. Woodard, Reference # 99-0009, on the transportation of "Regulated Medical Waste, 6.2, UN 3291, PG II" by couriers.

The letter states "intrastate and interstate shippers and carriers, including couriers of hazardous materials, which includes certain RMW, are subject to the HMR. Examples of waste materials that are excepted from regulation under the HMR are waste from households, and corpses or anatomical remains intended for cremation or interment".

I request a clarification on what constitutes household waste and what appears to be the exception of HMR for couriers who remove RMW from households. I raise this issue because I believe this is inconsistent with your regulations.

Your statement above clearly indicates couriers of hazardous materials are subject to the HMR - removal of RMW from a doctor or dentist's office by a courier service requires compliance with the HMR. I believe the logic that applies here is what is the waste (RMW), who is generating the waste (healthcare professional), and who is removing the waste (courier).

Would not the same logic apply to RMW generated in the home by the same health care professional and transported in commerce by the same courier service?

The use of home health care has expanded not only in the U.S but also across the world. Procedures, services, and treatment once conducted in the acute care setting are now occurring in offices and residences. The resulting waste stream generated pursuant to these services includes but is not limited to sharps and chemotherapeutic agents in both settings. In both instances, the healthcare professionals generate the same hazardous material. In both instances, the courier would be transporting the same type of hazardous material. These couriers are conducting transportation in commerce.

I believe the exception for waste from households, which you referenced in your letter to Dr. Woodard, applies to waste actually generated by the homeowner as a consequence of the homeowner's personal healthcare and disposed of by the homeowner along with other non-

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hazardous household waste. I would agree it is unrealistic and impossible to regulate the individual homeowner. In most instances, the US EPA does not regulate hazardous waste generated by the homeowner for purely practical reasons. This is addressed by programs in place at the local level to assist homeowners in the disposal of hazardous waste materials and other hazardous materials they may accumulate. I note emphasis on who is generating the waste and the transportation in commerce of that waste.

The movement of health care from the acute care setting to the home environment has now placed large volumes of RMW into the stream of commerce. The health care provider is creating the waste stream by virtue of the medical services provided. The organizations providing services to patients are also the same entities delivering and removing supplies to be used on those patients. The success of these companies depends on the timely and efficient deliver of products and services. Those products and services are provided by means of commercial transportation. It is as much a transportation business as it is a health care provider business.

I look forward to your response.

Regards

Edward Krisiunas, MT(ASCP), CIC, MPH

Director

Cc: Alan Roberts, RSPA

Ed Mazzulo, RSPA

Alan Woodard, Ph.D., NYSDEC